RFP Number : N02CM47001-42 Amendment 4

OFFICE OF ACQUISITIONS NATIONAL CANCER INSTITUTE

REQUEST FOR PROPOSAL NUMBER: N02CM47001-42

Amendment No.: 4

Date of Issuance: 10/31/2014

The above numbered Request For Proposal (RFP) is amended as set forth below. The hour and date specified for receipt of Offerors is changed to.

Offerors MUST acknowledge receipt of the amendment prior to the hour and the date specified in the solicitation or as amended, by separate letter, telegram, or Electronic Mail which includes a reference to the RFP and Amendment number(s). For your convenience, the Proposal Intent Response Form is provided in SECTION J - List of Attachments of this RFP, for this purpose.

FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERORS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER.

This Amendment answers additional questions about the solicitation. The questions and answers are below:

1. Reference 14.B.1.b.4 - Please provide the Government's definition of Key Personnel for this proposal.

Answer: All Key Personnel positions are listed on Page 72-73 of the solicitation under Section M 4(A).

2. Sample Task 4 page 210- What is the final disposition of the dogs? Is there any necropsy or gross pathology required?

Please note that these are "sample" task orders. Actual task orders will be tailored to the molecule being studied.

Answer: Assume that there will be no necropsy for this sample protocol. A necropsy (or pathology) may be needed if there is an unanticipated death and may be requested only if that occurs.

3. Section F - There are a number of reports due to the NCI at a contract level (Section 508, annual utilization report, semi-Annual financial report, final report at end of contract, final invention statement, animal assurance report), how will these be funded? At a separate administrative task orders level?

Answer: Past experience shows that most contractors build these reports into their in-direct costs. With that being said, no administrative task orders will be issued. Lastly, the calculation of the in-direct cost rate agreement it is up to each contractor's individual approved accounting system as well as confirmation\approval from DFAS.

4. Sample task orders - all protocols indicate the animals will be supplied by the NCI, in the past the CRO had to purchase the animals. Should animal purchase price be included in the cost assumptions?

Answer: Yes.

5. Sample task orders - formulation preparation is not mentioned. Will preparation be required or will the test article be sent ready for use?

Answer: Include preparation for costing.

6. Sample task orders - in the reporting section there is a statement for monthly reports. Is this a contract level report or each study?

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Answer: A study report.

7. Sample task orders - species strain of rats. All previous work was with Sprague-Dawley rats. Is the Fisher 344 rat correct?

Answer: The strain will be provided in the protocol/SOW from the NCI for the actual TO. Feel free to use Sprague-Dawley for costing.

8. Sample task orders - for those studies with plasma collected for drug concentration analysis there is no statement as to who will analyze and report and subsequently report TK analysis results (i.e collect and ship to the NCI for analysis or perform in house based on a validated method provided by the NCI?)

Answer: For the sample TO, assume you will analyze and report results. As stated earlier these are sample task orders, the actual source for analysis will be clearly designated for each independent TO.

9. For GLP studies should method development and validation be included as a separate item for dose formulation analysis and bioanalytical analysis?

Answer: For costing, yes.

10. Amendment 3 includes a question in regards to SCA. IAW the FAR, the government provides the appropriate Wage Determination. Will the Wage Determination be provided on an individual task order basis?

Answer: If applicable, the Wage Determination will be provided on an individual task order basis. Please note that SCA may not be applicable. Applicability of SCA depends on the contractors approved accounting system and the proposed personnel.

11. Article C.3 requires Invention Reporting IAW FAR 52.227-11. Under Article I.2(b) the FAR IP clauses are expected to be deleted. Please clarify the intent of the Government. Is the clause and reporting included?

Answer: Article I.2(b) is only applicable for non R&D contracts with educational institutions and/or nonprofit organizations.

12. Article G.6 sets forth the cognizant Contracting Officer to negotiate provisional/final rates. However, if a contractor has an ACO that performs this function for all government contracts, is it acceptable to replace G.8 with the contractor ACO?

Answer: If a contractor has a rate agreement through DFAS/NCI, DCMA or another federal government agency, that rate agreement will be honored.

13. Please clarify as to whether Certified Cost or Pricing data is required for this solicitation since there is an expectation of competition.

Answer: Please reference page 58 of the solicitation "This cover sheet information is for use by offerors to submit information to the Government when certified cost or pricing data are not required but information to help establish price reasonableness or cost realism is necessary. Such information is not required to be certified in accordance with FAR 15.406-2." Accordingly, Certified Cost or Pricing data is not required for this solicitation but "Requirements for Certified Cost or Pricing Data and Data Other than Certified Cost or Pricing Data, FAR Clause 52.215-20 (October 2010)" must be followed.